Kentucky Department for Medicaid Services
Drug Review and Options for Consideration

The following table lists the agenda items scheduled for review, as well as options for consideration, at the May 19, 2016 meeting of the Pharmacy and Therapeutics Advisory Committee.

Item	Options for Consideration

New Products to Market:
Zembrace™ SymTouch™
	Non-prefer in PDL class: *Antimigraines, Triptans*
	Length of Authorization: 1 year
	Zembrace™ SymTouch™ (sumatriptan succinate) Injection, for subcutaneous use is a serotonin (5-HT1B/1D) receptor agonist (triptan) indicated for: Acute treatment of migraine with or without aura in adults.
	• Is there any reason that the patient cannot be switched to a preferred medication? Document the details. Acceptable reasons include:
	  ○ Adverse reaction to all preferred drugs
	  ○ Allergy to all preferred drugs
	  ○ Contraindication to all preferred drugs
	• Has the patient had a documented therapeutic trial and treatment failure with ALL preferred drugs? If so, document the details.
	• Sumatriptan generic oral and vial; Imitrex® Nasal; and Imitrex® Pen and Cartridge are covered without PA; clinical reason as to why sumatriptan generic oral and vial; Imitrex® Nasal; and Imitrex® Pen and Cartridge cannot be used.
	Quantity Limit = 8 units per month (to match all other pens/cartridges)

New Products to Market: **Vraylar™**	Non-prefer in the PDL class: *Antipsychotics* **Length of Authorization:** 6 months Vraylar™ (cariprazine) capsules, for oral use Indicated for: Acute treatment of manic or mixed episodes associated with bipolar I disorder OR treatment of schizophrenia. • Have a diagnosis of schizophrenia or for acute treatment of manic or mixed episodes associated with bipolar I disorder. • Had a failed 14 day trial of BOTH risperidone and one other atypical antipsychotic (i.e. Seroquel, Abilify, Clozaril, Invega, Zyprexa, Geodon…HIC3 H7T or H7X), OR medical justification why a trial is not appropriate. **Minimum Age =** 18 years of age or older **Quantity Limit** = 1 per day
New Products to Market:	Non-prefer in PDL class: *Hepatitis C*

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Zepatier™	**Length of Authorization:** depends upon regimen Zepatier™ (elbasvir and grazoprevir) tablets, for oral use is a fixed-dose combination product containing elbasvir, a hepatitis C virus (HCV) NS5A inhibitor, and grazoprevir, an HCV NS3/4A protease inhibitor, and is indicated with or without ribavirin for treatment of chronic HCV genotypes 1 or 4 infection in adults. • Indicated with or without ribavirin for treatment of chronic HCV genotypes 1 or 4 infection in adults. • Must supply proof of genotypes 1 or 4 along with documentation of F3 or F4 fibrosis score. • Documentation of *Readiness to Treat* is also required. Test patients with HCV genotype 1a infection for the presence of virus with NS5A resistance associated polymorphisms prior to initiation of treatment with Zepatier to determine dosage regimen and duration. • The safety and efficacy of Zepatier have not been established in patients awaiting liver transplant or in liver transplant recipients. • Zepatier is contraindicated in patients with moderate hepatic impairment (Child-Pugh B) and in patients with severe hepatic impairment (Child-Pugh C). **Minimum age** = 18 years **Maximum Quantity Limit** = 1 per day

New Products to Market:
Adzenys XR-ODT™
	Non-prefer in PDL class: *Stimulants & Related*
	Length of Authorization: 1 year
	Adzenys XR-ODT (amphetamine extended-release orally disintegrating tablets), CII is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older.
	• Is there any reason that the patient cannot be switched to a preferred medication? Document the details:
	  ○ Adverse reaction to preferred drugs
	  ○ Allergy to preferred drugs
	  ○ Contraindication to preferred drugs
	• Has the patient had a therapeutic trial and treatment failure with **TWO** preferred drugs? Document the details.
	• Patient has a swallowing disorder and cannot be given tablets or capsules.
	Minimum age = 6 years
	Quantity Limit = 1 per day

New Products to Market:
Dyanavel™ XR
	Non-prefer in PDL class: *Stimulants & Related*
	Length of Authorization: 1 year
	Dyanavel XR (amphetamine) extended-release oral suspension, CII is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).
	• Is there any reason that the patient cannot be switched to a preferred medication? Document the details:
	  ○ Adverse reaction to preferred drugs
	  ○ Allergy to preferred drugs
	  ○ Contraindication to preferred drugs

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	• Has the patient had a therapeutic trial and treatment failure with **TWO** preferred drugs? Document the details. • Patient has a swallowing disorder and cannot be given tablets or capsules. **Minimum age** = 6 years **Quantity Limit** = 20mg/d (2.5mg/mL)

New Products to Market:
QuilliChew ER™
	Non-prefer in the PDL class: *Stimulants & Related*
	Length of Authorization: 1 year
	
	QuilliChew ER™ (methylphenidate hydrochloride) extended-release chewable tablets, for oral use, CII: QuilliChew ER is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).
	• Is there any reason that the patient cannot be switched to a preferred medication? Document the details:
	  ○ Adverse reaction to preferred drugs
	  ○ Allergy to preferred drugs
	  ○ Contraindication to preferred drugs
	• Has the patient had a therapeutic trial and treatment failure with **TWO** preferred drugs? Document the details.
	• Quillivant XR and Methylin Chewable Tablets are covered as preferred; clinical reason as to why Quillivant XR and Methylin Chewable Tablets cannot be used.
	
	Minimum age = 6 years
	Quantity Limit = 1 per day (1QAM)

Acne Agents, Topical	• DMS to select preferred agent (s) based on economic evaluation; however, at least multiple generic formulations of benzoyl peroxide, one topical antibiotic agent for acne and tretinoin should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the Topical Acne Agents class, require a PA until reviewed by the P&T Advisory Committee.
Antivirals, Oral	FLU: • DMS to select preferred agent (s) based on economic evaluation; however, at least amantadine (Antiparkinson's class), oseltamivir, and zanamivir should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • DMS to consider CDC recommendation updates regarding antiviral therapy for the treatment of influenza. The Medical Director, with Commissioner approval, may make changes to the PDL listing based on the CDC recommendations until this class can be considered at the next scheduled review. • For any new chemical entity in the Antivirals, Oral class, require a PA until reviewed by the P&T Advisory Committee. HSV: • DMS to select preferred agent (s) based on economic evaluation; however, at least acyclovir and either valacyclovir or famciclovir

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	should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the Antivirals, Oral class, require a PA until reviewed by the P&T Advisory Committee.
Bone Resorption Suppression & Related	• DMS to select preferred agent (s) based on economic evaluation; however, at least alendronate, calcitonin-salmon and raloxifene should be preferred on the PDL. Additionally, at least one bisphosphonate with a once-weekly dosing formulation should be preferred on the PDL • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the Bone Resorption Suppression and Related Agents class, require a PA until reviewed by the P&T Advisory Committee.
Cytokine & CAM Antagonists	• DMS to select preferred agent (s) based on economic evaluation; however, at least two self-administrable products should be preferred. • Agents not selected as preferred will be considered non-preferred and require trial and failure of preferred product (s) with an FDA-approved indication for the requested diagnosis. • All agents in the category should be approved for their FDA-approved indications only. • Allow continuation of therapy for non-preferred single-source branded products. • Maintain quantity limits on agents within the category according to their maximum recommended dose, taking into consideration any escalating doses needed during initial therapy. • For any new chemical entity in the Cytokine and CAM Antagonists and Related Agents class, require a PA until reviewed by the P&T Advisory Committee. Note: Taltz as NPD will have length of authorizatin of 1 year with standard NPD product criteria of; document why a preferred agent cannot be used.
Glucocorticoids, Inhaled	• DMS to select preferred agent (s) based on economic evaluation; however, at least three unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. • Continue quantity limits on agents in this class. • Continue to allow budesonide respules without PA for patients less than 8 years of age. • For any new chemical entity in the Glucocorticoids, Inhaled class, require a PA until reviewed by the P&T Advisory Committee.
Glucocorticoids, Oral	• DMS to select preferred agent (s) based on economic evaluation; however at least generic formulations of budesonide, dexamethasone, methylprednisolone, prednisolone and prednisone should be preferred. • The orally disintegrating formulation of prednisolone should be available for children < 12 years of age. • Agents not selected as preferred will be considered non preferred and require PA. • For any new chemical entity in the Oral Steroids class, require a PA until reviewed by the P&T Advisory Committee.

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Growth Hormone	• DMS to select preferred agents based upon economic evaluation; however, one preferred agent should be supplied in a pediatric convenient dosing form. • Continue to require clinical PA for all agents, preferred or non-preferred. • For any new chemical entity in the Growth Hormone class, require a PA until reviewed by the P & T Advisory Committee.
Hepatitis B	• DMS to select preferred agent (s) based on economic evaluation; however, at least entecavir and lamivudine should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the Hepatitis B Agents class, require a PA until reviewed by the P&T Advisory Committee.
Immunomodulators, Atopic Dermatitis	• DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the Immunomodulators, Atopic Dermatitis class, require a PA until reviewed by the P&T Advisory Committee.
Immunosuppressives, Oral	• DMS to select preferred agent (s) based on economic evaluation; however, at least four unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. • DMS to allow continuation of therapy if there is a paid claim in the past 90 days. • For any new chemical entity in the Immunosuppressives, Oral class, require a PA until reviewed by the P&T Advisory Committee.
Multiple Sclerosis Agents	• DMS to select preferred agent (s) based on economic evaluation; however, at least glatiramer, one interferon ß-1b and one interferon ß-1a product should be preferred. • Agents not selected as preferred will be considered non preferred and require PA. • Place quantity limits on these products based on maximum recommended dose. • For any new chemical entity in the Multiple Sclerosis Agents class, require a PA and quantity limit until reviewed by the P&T Advisory Committee.
Pancreatic Enzymes	• DMS to select preferred agent (s) based on economic evaluation; however, at least one pancreatic enzyme product should be preferred. • Agents not selected as preferred will be considered non preferred and require PA. • For any new chemical entity in the Pancreatic Enzyme class, require a PA until reviewed by the P&T Advisory Committee.
Progestins for Cachexia	• DMS to select preferred agent (s) based upon economic evaluation; however, at least one unique chemical entity must be preferred. • Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. • For any new chemical entity in the Progestins for Cachexia class, require a PA until reviewed by the P&T Advisory Committee.
Steroids, Topical Very High	• DMS to select preferred agent (s) based on economic evaluation; however, at least one agent in each of the potency categories (low, medium, high and very high) should be preferred.

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High **Medium** **Low**	• Agents not selected as preferred will be considered non preferred and require PA. • For any new chemical entity in the Topical Steroids class, require a PA until reviewed by the P&T Advisory Committee.
VIBERZI criteria Clarification	From the MAR 2016 mtg, there was a question on criteria regarding covered antidiarrheals. The covered products include: **RX**: loperamide, diphenoxylate/atropine liq & tab. **OTC**: loperamide. **Options for Viberzi**: trial and failure of at least 2 covered antidiarrheals.